DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 3 2001 2948

Food and Drug Administration
Rockville MD 20857

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David L. Dyer, Ph.D.
Director
Research and Development
Woodward Laboratories, Inc.
11132 Winners Circle, Building 100
Los Alamitos, CA 90720

Re: Docket No. 75N-183H/CP4

Dear Dr. Dyer:

This letter is sent in reference to your citizen petition dated August 4, 2000, which is filed as CP4 in Docket No. 75N-183H in FDA's Dockets Management Branch. . The petition requests that FDA amend the Tentative Final Monograph (TFM) for Over-the-Counter (OTC) Health-care Antiseptic Drug Products (June 17, 1994, 59 FR 31402) to include benzalkonium chloride (0.11 to 0.13 percent) as a generally recognized safe and effective active ingredient for use in OTC antiseptic hand sanitizer products.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR §10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR §10.30(e).

Your petition is one of a number of petitions requesting amendment of the TFM. The agency is in the process of evaluating the petitions and comments submitted to the public docket and their impact on the development of a final rule for OTC health-care antiseptic drug products. Consequently, we are unable to provide a final decision on the merits of your request within 180 days of the date your request is filed. However, resolution of the pending petitions for this rulemaking are important, and a response to your petition will be provided at a later date.

If you have any questions regarding this matter please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Jane A. Axelrad for JW

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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